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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,463	11/23/2005	Ying Zhang	200507001-1	3795

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YUAN QING JIANG
P.O. BOX 61214
PALO ALTO, CA 94306

EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,463	ZHANG ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 0725*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4-6 and 14* is/are allowed.

6)☒ Claim(s) *1-3 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 07/25/07.

The amendment filed 07/25/07 affects the application, 10/538,463 as follows:

1. Claims 1-6 and 8-10 have been amended. Claim 8 has been canceled. New claims 11-14 have been added.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-6, 8-14 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the phrase "a disease characterized as hypertension". However, this phrase renders the claim indefinite since it is unclear what diseases are characterized as hypertension and whether or not applicant intends to treat hypertension or some other diseases. Also, it is unclear if applicant intends to treat diseases that are not hypertension even if they are wrongly characterized as being hypertension.

Claim 9 recites a method of protecting skin or hair ab administering a given composition.. however, the claim is indefinite since it is unclear what is protecting the skin or hair of said subject from. Furthermore, it is unclear what constitutes a protection especially since it is unclear from what is skin or hair is being protected.

Claim 10 recites the phrase "a disease characterized as carcinoma". However, this phrase renders the claim indefinite since it is unclear what diseases are characterized as carcinoma and whether or not applicant intends to treat carcinoma or some other diseases. Also, it is unclear if applicant intends to treat diseases that are not carcinoma even if they are incorrectly characterized as being hypertension.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally

known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

Claim 10 is drawn to a method of preventing or treating a disease characterized as carcinoma, comprising administering to a subject suffering from said disease a therapeutically effective amount of total triterpenoid sapogenins as defined in claim 1, wherein said therapeutically effective amount of total triterpenoid sapogenins is administered orally in medicine or food. Dependent claim 11 is darn to the said method wherein specific triterpenoid sapogenins is used.. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicant claims are drawn to method of preventing a disease characterized as carcinoma, comprising administering to a subject suffering from said disease a therapeutically effective amount of total triterpenoid sapogenins as defined in claim 1, wherein said therapeutically effective amount of total triterpenoid sapogenins is administered orally in medicine or food, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease, which is seen to be lacking a clear

description via art recognized procedural and methodological steps. In addition, the prevention of such diseases (carcinoma or cancers) does not have a single recognized cause. In fact, the aforementioned diseases, is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) cigarette smoking and (2) family history of cancers. These are only a few of the factors that promote cancers in people. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. For example the prevention or treatment of carcinoma or cancer in a subject is not enabled because of the following. One cannot extrapolate the teaching of the specification to the claims because it is well known that the art of anticancer drug discovery for cancer therapy is highly unpredictable. For example, Gura (Science, 1997, 278(5340):1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and

that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). In addition, Hartwell et al (Science, 1997, 278(5340):1064-1068) teach that an effective chemotherapeutic must selectively kill tumor cells, that most anticancer drugs have been discovered by serendipity and that the molecular alterations that provide selective tumor cell killing are unknown and that even understanding the detailed molecular mechanism by which a drug acts often provides little insight into why the treated tumor cell dies (para bridging pages 1064-1065) and Jain (cited supra) specifically teaches that systemic treatment typically consists of chemotherapeutic drugs that are toxic to dividing cells (p. 58, col 2, para 2). Furthermore, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor or metastatic promotor producing cells and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time. It is clear, as disclosed above that the specification does not teach how to make or use a formulation with a targeting molecule. Also, the target cell must not have an

alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The formulation may be inactivated in vivo before producing a sufficient effect, for example, by degradation, immunological activation or due to an inherently short half-life of the formulation. In addition, the formulation may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the formulation has no effect, circulation into the target area may be insufficient to carry the formulation and a large enough local concentration may not be established. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. Therefore, the prevention of the said diseases (carninomas or cancers) in a subject is not enabled by the instant disclosure.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 12, 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6).

In claim 1, applicant claims A composition comprising a substantial amount of total triterpenoid sapogenins extracted from bamboo, wherein the substantial amount is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-3 5% friedelin and 1-10% lupenone as determined by GC-MS. Claim 2 is drawn to the composition of claim 1, wherein the content of total triterpenoid sapogenins is 40-80%, and the content of friedelin and lupenone are 15-25% and 3-6%, respectively. Claim 3 is drawn to the composition of claim 1 wherein the total triterpenoid sapogenins comprise pentacyclic triterpenids of friedelin, lupenone and their homologous compounds and wherein the triterpenod sapogenins have physical properties and gives specific IR and UV spectrograms. Claims 12 and 13 which are drawn said triterpenoid sapogenins composition.

Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). It should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et al. do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Ohmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin

and lupenone. Furthermore, it should be noted that Ohmoto et al.'s composition is obtained from the same source as applicant's composition and comprises the same components or substances (friedelin and lupenone) as applicant's composition and consequently may well have the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. anticipates the claims if their composition has the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. renders the claims as being obvious if the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in their composition is substantially close to the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in applicant's composition. Claims 2, 3, 12 and 13 are also encompassed by this rejection since Ohmoto et al. composition also comprises other pentacyclic triterpenoids and since Ohmoto et al silent about the physical properties and the IR and UV spectrograms of their composition does not mean that their composition does not have the same physical properties and the same IR and UV spectrograms as applicant's composition.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 4-6, 14 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a extracting total triterpenoid sapogenins from bamboo comprising specifically defined steps wherein the total triterpenoid sapogenins composition produced comprises specific total triterpenoid sapogenins, comprising specific friedelin and lupenone. The very relevant prior art (Staack Reis Machado et al. (EP 1122259 A2) document does not disclose or suggest the method of the instant that comprises the

specific steps claimed therein. Also the prior art uses a different source or starting material to obtain said total triterpenoid sapogenins composition.

Response to Arguments

Applicant's arguments with respect to claim 1-3, 12 and 13 have been considered but are not found convincing.

The applicant argues (that as it can be seen a table presented by applicant), the reference of Ohmoto et al. does not teach or suggest the composition comprising a substantial amount of total triterpenoid sapogenins extracted from bamboo, wherein the substantial amount is 10-90%. However, the bamboo used by Ohmoto et al. (which is Arundinarieae) is not the same the (Phyllostachys bambusoides sieb et Zucc var aurea Makino) presented in applicant's table. Consequently, applicant has not provide convincing evidence or facts that Ohmoto et al.'s composition is different from applicant's

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

10/15/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

October 15, 2007.